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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/813,783

03/30/2004

Henrik S. Klint

10921/27

5211

7590

12/22/2006

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EXAMINER :

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

12/22/2006

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/813,783

Applicant(s)

KLINT ET AL.

Examiner

Julian Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20 is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-19 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 5, 7, 9-11, and 14-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Ritchart et al. (4,994,069). Ritchart et al. disclose, at least in figures 1, 2B, 2C, and 8A-8D and in col. 8, lines 20 to col. 9, line 21, a method for endovascular occlusion of a blood vessel area (72) or vessel lumen, where the method includes, inter alia, advancing a catheter (12) in a blood vessel; pushing a wire body (14) through the catheter, the wire body including a front end, a back end and a substantially straight section larger than a diameter of the blood vessel area; abutting a first wall portion of the blood vessel area; continuing to push the wire body out of a distal opening of the catheter, thereby by curving the section of the wire body toward a second wall portion of the blood vessel area, and frictionally locking the section to the first and second wall portions and forming a portion of the wire body that crosses the blood vessel area or a complexly curved shape without breakpoints, where the front end of the wire is curved in an unloaded condition at least 120 deg., and the back end of the wire is curved in an unloaded condition between 140 deg. and 340 deg. and where the wire body is made of thread extending helically around a center line of the wire body and absent of occlusion hairs (see fig. 2B).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-4 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGurk et al. (5,690,671). McGurk et al. disclose, at least in figures 1, 2, and 6-11 and in col. 7, lines 20-52, a method for endovascular occlusion of a blood vessel area or aneurysm substantially as claimed. McGurk et al. disclose the method including, inter alia, advancing a catheter (20) in a blood vessel or to an aneurysm; pushing a wire body (10) through the catheter, the wire body including a front end, a back end and a substantially straight section larger than a diameter of the blood vessel area or aneurysm; and continuing to push the wire body out of a distal opening of the catheter, thereby by curving the section of the wire body toward a second wall portion of the blood vessel area, and forming a portion of the wire body that crosses the blood vessel area or forms curvatures in a complexly curved shape, where the wire body is made of

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a thread extending helically around a center line of the wire body and is absent of occlusion hairs, and where the front end (at 14) of the wire body is curved and is curved in at least 120 deg. in an unloaded condition and the back end (at 14) is curved in at least 120 deg. in an unloaded condition. However, McGurk et al. do not specifically disclose that the wire body abuts a first wall portion of the blood vessel area or aneurysm and that the front end and the section are frictionally locked against wall portions of the blood vessel area or aneurysm. Nevertheless, McGurk et al. teach that the entire internal volume of an aneurysm should be filled by at least one wire body. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply a wire body in an aneurysm, such that the front end and the section of the wire body are sized to abut a first wall portion of the blood vessel area or aneurysm and are frictionally locked against wall portions of the blood vessel area or aneurysm. Such a modification in the method of McGurk et al. would ensure that the wire body remains in place within an aneurysm and at least begin to fill the entire internal volume of the aneurysm.

5. Claims 6, 12, 13, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritchart et al. (4,994,069). Ritchart et al. disclose the invention substantially as claimed, but do not disclose retracting the catheter between the abutting and continuing steps, that the section has a length of at least 20 mm or 90 mm, that the wire body has a spring constant as claimed, and that the wire body is dimensioned as claimed. However, Ritchart et al. disclose that the wire body is biased in seemingly random directions as it is released from the catheter. Thus, it would have

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been obvious to one having ordinary skill in the art at the time the invention was made to retract the catheter between the abutting and continuing steps. Such a step would allow a surgeon to reposition the catheter, so that the catheter distal end does not interfere with the random, space-filling conformation of wire body within the blood vessel area. It also would be a matter of obvious design choice to size the section and the rest of the wire body as claimed, since such modifications would have involved mere changes in the size of a component. A change in size is generally recognized as being within the skill of ordinary skill in the art. Moreover, it would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the wire body, so that it has a spring constant as claimed, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (e.g., of a spring constant) involves only routine skill in the art.

Allowable Subject Matter

6. Claim 20 is allowed.

7. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses a method for endovascular occlusion of a blood vessel lumen, where the method includes, inter alia, advancing a catheter through a blood vessel, providing a wire body comprising a front end, a back end, a section connecting the front and back ends, the front end in an unloaded condition being formed as a spiral with a decreasing helix diameter in a direction of the front end, the section being at least six times the diameter of the blood vessel lumen, and the wire body being made of a thread extending helically around a center line of the

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wire body; and pushing the wire body forward through the catheter and abutting a first wall portion of the blood vessel lumen with the front end of the wire body.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

8. Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a method for endovascular occlusion of a blood vessel area, where the method includes, inter alia, advancing a catheter through a blood vessel, providing a wire body comprising a front end, a back end, a section connecting the front and back ends, the front end in an unloaded condition being formed as a spiral with a decreasing helix diameter in a direction of the front end and the section being at least six times the diameter of the blood vessel lumen; and pushing the wire body forward through the catheter and abutting a first wall portion of the blood vessel lumen with the front end of the wire body.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

10. Applicant's arguments filed on October 16, 2006 have been fully considered but they are not persuasive. With respect to arguments regarding the rejection based on the Ritchart reference: Ritchart indeed discloses, in figures 2A and 3A and in col. 3, line 63 to col. 4, line 5 and col. 8, lines 39-51, a wire body including a section that is "substantially straight in an unloaded condition." That is, before (and during) loading of the wire body into a catheter, the wire body is substantially straight, whether in a "stretched...linear condition" or a "straight rigidified form" when packaged and presented to a surgeon. Similarly, with respect to arguments regarding the rejection based on the McGurk reference: McGurk discloses, in figure 1, a wire body that is "substantially straight in an unloaded condition" (at room temperature). McGurk's wire body only assumes the nonlinear preset shape after deployment and after heating of the wire body above room temperature.

The rejection under 35 U.S.C. 112, 2nd paragraph is hereby withdrawn.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

December 12, 2006